

EXHIBIT 33

McPherson, Carolyn

From: Reardon, Steve
Sent: Friday, September 14, 2007 9:17 AM
To: Brantley, Eric; McPherson, Carolyn; Trautman, Elaine; Bennett, Don; Mohn, Al; Lyle, Don
Cc: Grant, Claude; Duffy, Mike; Strizzi, Dave; Giacalone, Robert
Subject: DEA Suspicious Order Monitoring

Attachments: Final Summary of DEA Meeting 9-7-07.doc; DEA Presentation.pdf

HDMA met with DEA officials last Friday September 7 to discuss the Agency's current policy position on suspicious orders of controlled substances. A summary highlighting the key points made during the meeting are attached for your review. DEA is setting a new standard with which we must comply. This is all coming about as a result of the problems with internet pharmacies and controlled substance diversion. Recently, they suspended an ABC registration and used the suspension to get them to implement a complex and onerous suspicious order monitoring program that meets the criteria spelled out in the HDMA meeting summary. ABC presented their program at the DEA Industry conference this week that I attended and I have attached a copy of the presentation. DEA referred to the ABC program as the new industry standard. I will be setting up a meeting to initiate discussions on this topic in the near future.

Additionally, I am aware that MCK is in ongoing negotiations with DEA related to an Order to Show Cause. An Order to Show cause affords a registrant the opportunity to argue why a registration should not be suspended or revoked. I think it would be safe to assume that DEA will use this opportunity to get MCK to implement an ABC like program. Also, at the industry meeting the HD Smith Director of Regulatory Compliance was pulled aside and told that DEA has a concern with some of their customers and to schedule a meeting with DEA in DC to discuss and that he should bring his IT people with him.

We need to be proactive and implement a program that we develop, that will satisfy DEA expectations and that is not dictated to us by the Agency pursuant to regulatory action. The ABC program is not customer friendly and results in delayed filling and delivery of controlled substance orders to the customer.

Steve



Final Summary of
DEA Meeting 9... .sentation.pdf (389 I



DEA

Stephen J. Reardon
Vice President
Quality & Regulatory Affairs
Healthcare Supply Chain Services
Cardinal Health
7000 Cardinal Place
Dublin, Ohio 43017
Tel 614-757-7101
Fax 614-652-4264
Cell 614-668-2044
steve.reardon@cardinal.com

Summary of the DEA-HDMA Meeting on Suspicious Orders
Meeting Date: Sept. 7, 2007

HDMA Attendees: Scott Melville, Anita Ducca, David Durkin (OFW)

DEA Attendees: Mark Caverly, Kathy Gallagher, Mike Mapes, Lisa Sullivan

Summary: After introductions, HDMA

- Gave a brief overview of the Association, the Distribution industry, and described some of HDMA's safety policies and initiatives.
- Indicated our interest in having the DEA explain their "Internet Distributor Initiative" and understanding the DEA's expectations.

DEA then provided us with their latest organization chart and explained the responsibilities of each section. Mike Mapes then provided HDMA with the same presentation that DEA has provided to several wholesale distributors regarding suspicious orders. (Attached) He noted that DEA had met with approximately 15-20 wholesale distributors one-on-one. They had prioritized who to meet with on a combination of wholesale distributor sales volume and tracing back to where they felt the source of products for illicit Internet pharmacies were located.

Key "take aways" from the meeting were:

- DEA's policy was to expect more than just reporting "suspicious orders". If there was a suspicious order, the distributor should either stop the delivery or should evaluate the customer further before delivering it.
- Simply complying with the "suspicious orders" regulatory requirement does *not* mean, in the agency's view, that the registrant is maintaining an effective program to detect and prevent diversion.
- DEA indicated that they did not have the resources to inspect every pharmacy; therefore it was important for the distributor to "know their customers."
- The DEA criteria reflected in their September 2006 letter to registrants was "for background" and they do not expect the wholesale distributor to violate privacy or other laws to find out what they needed to know about their customers.

Additional points DEA made included:

- DEA was clear that the "system" mentioned above did not need to be the same for each wholesale distributor.
- DEA provided examples of what a wholesale distributor should do to "know their customers" and what to look for. For example, they mentioned inspecting pharmacies. They also mentioned such actions as "doing Google searches" to determine if the pharmacy's name was affiliated with an internet site, and getting information from the state as to the nature and number of prior legal actions against a pharmacy. And they gave a checklist of "Internet Pharmacy Decision Questions" meant as a guide. (See attachment

Summary: 9-07-07 DEA/HDMA Meeting

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– page 2 after the organization chart) However, they did not give specifics as to how to go about completing the checklist beyond the examples above, and it was unclear if they expected wholesale distributors to inspect all pharmacies

- DEA also does not want to receive suspicious order reports that merely reflect volumes that went over a threshold; they wanted reports that are “true” suspicious orders. Similarly, they do not want to receive what they called “excessive purchase” reports which had been used in the past.
- DEA also indicated that they were not going to make a decision for the wholesale distributor as to when an order was “suspicious”. They feel this is up to the distributor.
- DEA suggested that distributors should check on the pharmacy’s prescribing physicians. They pointed to some states having on-line systems by which a distributor could check to see if a prescribing physician had a valid DEA registration. DEA suggested that distributors ask who the doctors are that are prescribing, where the pharmacy is geographically with respect to its prescribing doctors and the patient population.

Conclusion:

At the close of the meeting, HDMA indicated that we would be meeting with our members and discussing this further. We indicated that we might be suggesting future meetings between our two organizations and our members.

HDMA questions and assessment:

- DEA attempted to place the Sept. 2006 letter into a better light than what it appeared to be on its face.
- DEA’s expectations are clearly heightened. HDMA would like to ask its members about the impact of these expectations. For example,
 - Are all members capable of inspecting their pharmacy customers?
 - How difficult is it to put a “system” in place that not only monitors suspicious orders but also stops the order and/or evaluates the customer against the order?
 - How often does a suspicious order fall into a “gray area” for example, the order is larger than a pre-established threshold, but not so far over that it is clearly out of line with that pharmacy’s customer base and size?
- Do we need better clarification and/or a written statement from the DEA about when to send a suspicious order and when not to send it even if it is over a threshold?
- Do we have recommendations for DEA as to how to approach this problem in a way that simplifies things for the wholesale distributor? Would some of our anti-counterfeit policies fit this situation? E.g., ask them to support RFID? Recommend, (and press for) better pharmacy inspections by DEA prior to licensure?



**Drug Enforcement Administration
Pharmaceutical Industry Conference**

**Wholesale Distribution
Diversion Control Program**

September 11, 2007

**Chris Zimmerman
Vice President - Corporate Security & Regulatory Affairs
AmerisourceBergen Corporation**

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Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

**1301.71(a) - "All applicants and registrants
shall provide effective controls and procedures to
guard against theft and diversion of controlled
substances."**

Distributor Response: Develop policy to

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HOW?

Distributors usually implement policies that mirror the Code of Federal Regulations' requirements:

1301.72 - Physical Security Controls – vault / cage construction and alarm system requirements – No Problem

1304 – Records and Reports of Registrants – information, maintenance, and inventory requirements – No Problem

1305 – Orders For Schedule I & II Controlled Substances – ordering, filling, executing, and endorsing DEA Forms 222 – No Problem

1301.74 – Other Security Controls – make a good faith inquiry; report suspicious orders; report significant losses – gray area

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Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.74(b) - "The registrant shall design and operate a system to disclose to the registrant **suspicious orders** of controlled substances. The registrant shall inform Field Diversion Office of the Administration in his area of suspicious orders **when discovered** by the registrant."

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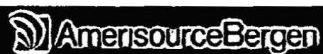
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Regulatory Responsibility

- ▶ Reporting suspicious orders to DEA does **NOT** relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- ▶ DEA cannot / will not tell a distributor:
 - if an order is or is not legitimate; and/or
 - if the distributor should or should not ship an order
- ▶ Distributor must make a “business” decision whether or not to ship the order.

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ABC's Diversion Control Program

- ▶ “Know Your Customer” Due Diligence
- ▶ Order Monitoring Program (OMP)
- ▶ Investigations
- ▶ Education and Training

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New Customer Due Diligence

- ▶ "Know Your Customer" Due Diligence investigations completed on all new Retail and Wholesale Accounts.
 - Retail chain pharmacies are exempted.
- ▶ Included in New Account Setup Process
 - New Account Questionnaire
 - On-site visit includes photographs inside and out (or physical description of premises)

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New Customer Due Diligence

- ▶ Monthly Sales Limits
 - All new accounts set at the lowest threshold level for DEA business type in ABC's Order Monitoring Program (OMP)
- ▶ "Do Not Ship" List
 - Customers to whom ABC has ceased distribution to due to suspicious activity
 - Other sources

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Order Monitoring Program (OMP)

- ▶ The Controlled Substances/Listed Chemicals Order Monitoring Program (OMP) was developed to identify suspicious orders and purchasing trends.
- ▶ Historically Controlled Substance / Listed Chemical order monitoring has been based on a **ship and report** process.
- ▶ ABC's OMP process is now based on: identify, capture, investigate, and report suspicious orders; all prior to shipment.

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OMP Customer Account Type and Size

- ▶ Each Customer is classified by "Customer Type," which represents how the customer is registered with DEA.
 - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
 - This value is loaded using the NTIS Database synch process.
- ▶ Each customer is then categorized by "Customer Size" based upon average revenue relative to its peers in the same "Customer Type."

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OMP Item Family and Threshold

- ▶ All controlled substance and listed chemical products are grouped into item "families" based upon the drug's active ingredient, which has a corresponding Generic Code Number (GCN).
- ▶ The OMP will combine all sales of items within the same GCN family (e.g., hydrocodone / vicodin; oxycodone / percocet; Alprazolam / Xanax), for each customer.

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OMP Item Family and Threshold

- ▶ Item threshold levels are established from accumulated monthly sales for all customers based on item family, DEA type, and customer size.
- ▶ A customer's threshold level is initially set by item family based on the customer's DEA type and customer size.

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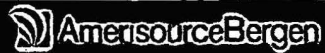
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OMP Order Processing

- ▶ A customer's incoming orders are accumulated by item family, and the total item family order quantity is applied to the predetermined Item family monthly threshold.
- ▶ If the order quantity falls below the Item family threshold, the order will process normally.

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OMP Order Processing

- ▶ If the order quantity goes over the item family threshold, the order will be placed into "OMP Review."
- ▶ All subsequent orders within the same item family will be rejected while an item within the same family is under review.
- ▶ Each distribution center (DC) is responsible for initial review of all orders in OMP Review.
 - If the DC can determine the order is not suspicious, the DC will release the order.
 - If the DC is unsure, the order will be flagged to be investigated by Corporate (CSRA).

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OMP Order Processing

- ▶ All OMP orders that the DC released, as well as those flagged for CSRA Review, are sent to CSRA each morning.
- ▶ Based upon information available to CSRA, flagged orders will either be released or placed in "Investigate" status.
- ▶ All orders placed into Investigate status are electronically reported to DEA on a daily basis.

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OMP Order Processing

- ▶ CSRA conducts the investigation and will notify the distribution center of the final disposition of the order (release or cancel).
- ▶ CSRA will also determine if any permanent action needs to be taken with the customer.
 - Customers who have legitimate needs will have their size or threshold levels increased.
 - Customers with continued suspicious ordering patterns may have their ability to order control substances effected.

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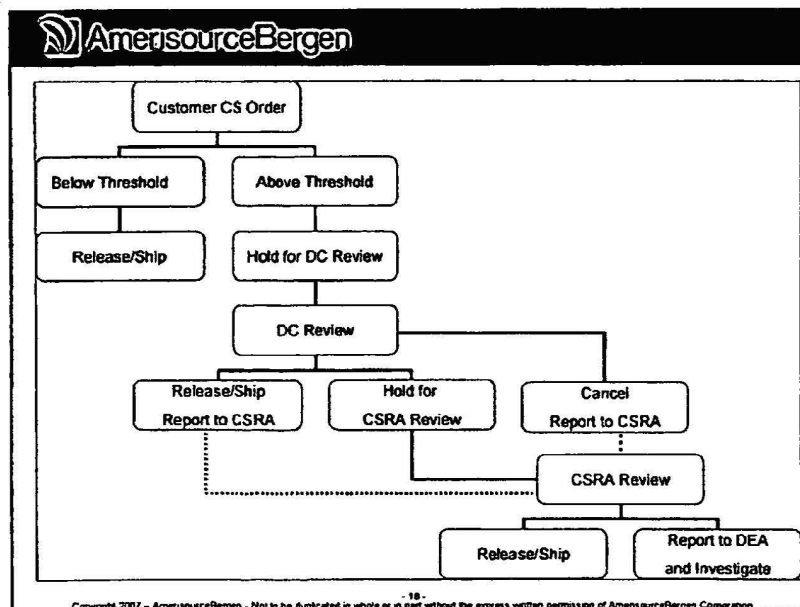
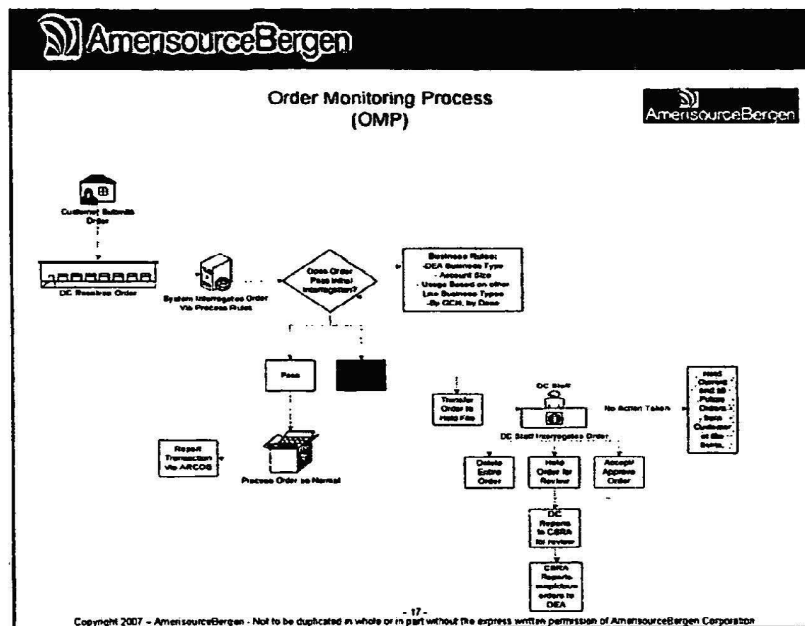
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Order Monitoring Program (OMP)

- ▶ A Distributor can't solely rely on computer systems and programs to prevent diversion.
- ▶ All employees have a role and responsibility in a successful Order Monitoring Program:
 - Sales
 - Procurement
 - Management (DC / HQ)
 - Order fillers
 - Customer service
 - IT

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Investigations

- ▶ Sources of Investigations
 - Order Monitoring Program (OMP)
 - Monthly Customer Product Mix Report
 - Notification by DEA
 - Notification by ABC DC
- ▶ Typical Investigation Process
 - One-year purchase history
 - On-site inspection
 - CSRA Form 590c Retail Pharmacy Verification Checklist
- ▶ Decision
 - Cease distribution of CS/LC to customer
 - Customer Sign applicable compliance agreement

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Education and Training

- ▶ All appropriate associates are trained on ABC's Diversion Control Program
- ▶ ABC also holds training and educational courses for its customers and vendors regarding this subject matter.



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Questions?

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